

EXHIBIT 617

Digitek

SUPPLY AND DISTRIBUTION AGREEMENT

This Supply and Distribution Agreement ("Agreement") is entered into this 5th day of

August, 1999 by and between:

Mylan Laboratories, Inc.
a Pennsylvania Corporation with an office located at 781
Chestnut Ridge Road
Morgantown, West Virginia 26505

and

Bertek Pharmaceuticals Inc.
a Texas Corporation,
(hereinafter collectively referred to as
"BERTEK") with offices located at
3711 Collins Ferry Road
Morgantown, West Virginia 26505

and

Amide Pharmaceuticals, Inc.
a New Jersey corporation,
(hereinafter referred to as
"AMIDE") with offices located at
101 East Main Street
Little Falls, New Jersey 07424

WHEREAS, BERTEK develops, manufactures, markets, sells, and distributes
pharmaceutical products; and

WHEREAS, AMIDE develops, manufactures, markets, sells and distributes
pharmaceutical products; and

WHEREAS, AMIDE wishes to enter into an agreement under which it will exclusively
deliver the Products (as hereinafter defined) to BERTEK, for marketing, sale and distribution, and
to provide other such rights as may be necessary and desirable to effectuate the purposes of this

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Agreement; and

WHEREAS, BERTEK wishes to enter into such an agreement with AMIDE under which BERTEK will market, sell, and distribute the Products for AMIDE, on an exclusive basis.

WITNESSETH THEREFORE that in consideration of the premises set forth and covenants exchanged herein and for other good and valuable consideration, the sufficiency and receipt of all of which are hereby acknowledged, BERTEK and AMIDE intending to be legally bound agree as follows:

I. DEFINITIONS

- 1.1 "Affiliate(s)" shall mean any corporation, association, company, organization or other entity which directly or indirectly controls, is controlled by or under common control with BERTEK or AMIDE, as the case may be. For purposes of this definition, control means the ability, directly or indirectly, through ownership of securities, by agreement, or by any other method, to direct more than fifty percent (50%) of the outstanding equity votes of any entity, whether or not represented by securities, or to otherwise control the management decisions of any entity.
- 1.2 "ANDA(s)" shall mean an abbreviated new drug application for the Products which has been submitted to or approved by the FDA, and which is owned by AMIDE.
- 1.3 "Bad Debt" shall mean such unrecovered payments for products sold, distributed or delivered by BERTEK, after BERTEK has used its "Commercially Reasonable Efforts" (as hereinafter defined) to collect any and all payments for such Products.
- 1.4 "BERTEK" as used in this Agreement shall mean BERTEK, Mylan Laboratories, Inc. and all affiliates and subsidiaries of any related company or entity.

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- 1.5 "cGMPs" shall mean Current Good Manufacturing Practices as defined in 21 CFR § 210 et seq., as amended from time to time.
- 1.6 "Calendar Quarter" shall mean those three (3) month periods beginning on January 1, April 1, July 1, and October 1.
- 1.7 "Commencement Date" shall mean the date first hereinabove entered.
- 1.8 "Commercially Reasonable Efforts" shall mean that degree of effort, expertise and resources which a person of ordinary skill, ability and experience in the matters addressed herein would utilize and otherwise apply with respect to fulfilling the obligations assumed hereunder.
- 1.9 "FDA" shall mean the Food and Drug Administration of the United States.
- 1.10 "FFDCA" shall mean the Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. §301 et seq., and any related federal and/or state law or regulation pertaining to the safety, effectiveness, adulteration, mishandling, packaging, labeling or storage of pharmaceutical ingredients, finished pharmaceutical products, and/or medical devices that may be applicable to the Products during the term of this Agreement.
- 1.11 "Gross Margin" shall mean Net Sales of the Products less the Manufacturing Cost.
- 1.12 "Intellectual Property" shall mean patent applications, continuations-in part, divisionals, trade names, trademarks, and trade dress.
- 1.13 "Law" shall mean any local, state or federal rule, regulation, statute or law relevant to the manufacture, distribution and/or sale of the Products, and to any other matters set forth herein.
- 1.14 "Losses" shall mean any liabilities, damages, costs or expenses, including reasonable

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attorneys' fees, incurred by either Party which arise from any claim, lawsuit or other action by a third party.

1.15 "Manufacturing Cost" shall mean AMIDE's actual cost of Raw Material (as hereinafter defined), direct labor and direct overhead.

1.16 "Reduced Residual Due" shall mean the amount of money calculated to be owed by BERTEK to AMIDE which shall equal ten (10%) percent of Net Sales as defined and set forth in 1.17.

1.17 "Net Sales" shall mean:

(a) with respect to commercial sales of the Products by BERTEK, its agents and Affiliates, the gross amount invoiced therefore, less

- (i) quantity and/or normal and customary cash discounts allowed or taken;
- (ii) freight, postage and insurance related to such sales;
- (iii) credits, rebates and/or adjustments allowed or given by reason of Products expiration dating, rejections or returns, shelf-stock adjustments, retroactive price reductions or programs with wholesalers or other distributors or resellers according to which they are entitled to chargeback rebates, credits or adjustments;
- (iv) rebates, administrative fees, reimbursements or similar payments to or for Medicaid or any other government programs (whether mandated or voluntary), hospitals, health maintenance organizations, insurance carriers, buying groups or other entities in connection with the purchase or utilization of Products; and

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(v) Bad Debt (as defined hereinabove).

1.18 "Party" or "Parties" shall mean BERTEK or AMIDE, or both, depending upon the context in which either word may appear.

1.19 "Product" or "Products" whenever used herein shall mean the pharmaceutical product or products either brand or generic identified in Exhibit A. Each dosage strength shall be considered a separate Product.

1.20 "Raw Material" shall mean bulk active ingredient digoxin, USP.

1.21 "Reporting Period" shall mean a three-month period.

1.22 "Specifications" shall mean all regulatory, manufacturing, quality control, and quality assurance procedures, processes, practices, standards, instructions and specifications comprising AMIDE's FFDCa approval applicable to the manufacture and packaging of Products as set forth in the ANDA, and such other FDA and/or other regulatory requirements as may be applicable.

1.23 "Territory" shall mean the United States of America, its Territories, Commonwealths and Possessions.

1.24 "Transfer Price" shall mean the prices at which AMIDE sells the Products to BERTEK as set forth in Exhibit B, and such prices shall be equal to AMIDE's Manufacturing Cost.

II. SCOPE OF AGREEMENT

2.1 Pursuant to the term and conditions set forth herein, AMIDE hereby grants to BERTEK the exclusive right to market, sell, promote and distribute the Products in the Territory. BERTEK shall purchase exclusively from AMIDE any and all such quantities of Products as BERTEK may require to market, sell, promote, and distribute the Products.

2.2 BERTEK shall use its Commercially Reasonable Efforts to market, sell, promote and

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distribute the Products (hereinafter collectively "Commercialize") and to implement programs for such Commercialization in the Territory. Provided however, that BERTEK shall not be deemed to have failed to abide by or have failed to perform in accordance with its Commercialization effort if BERTEK is prevented from performing or is hindered in its performance of any such Commercialization effort by any act or omission of AMIDE or as permitted under this Agreement.

2.3 BERTEK shall not Commercialize the Products outside the Territory or to any purchaser or distributee that BERTEK anticipates, or reasonably should anticipate, intends to utilize, resell or redistribute the Products outside the Territory, without the prior written approval of AMIDE.

2.4 In the event BERTEK learns or is advised that Products are being utilized, resold or distributed outside the Territory ("Non-Territorial Use"), BERTEK shall use its Commercially Reasonable Efforts to identify such third party(ies) responsible for such Non-Territorial Use. If Bertek identifies such third party(ies) within three (3) business days of the discovery of such third parties, it shall:

- a. advise AMIDE of the identity of such third party(ies) in writing; and
- b. advise such third party(ies) in writing to stop such Non-Territorial Use and provide AMIDE a copy of such notification.

2.5 BERTEK shall have the duty to sell Products with BERTEK's Label to Amide's existing Customer Kaiser Permanente ("Kaiser") and such continued sales shall not be a breach of this Agreement. AMIDE may direct and BERTEK shall deliver all Products with BERTEK's Label to Kaiser at the rates in accordance with any contract, agreement or

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purchase order that may be in existence as of the Commencement Date with Kaiser a copy of which is attached hereto as Exhibit D. Amide shall assist BERTEK in negotiations with Kaiser to establish terms which are consistent with BERTEK's other contract customers.

III. FORECASTS AND SUPPLY

- 3.1 (a) Both Parties agree to work together closely in order to ensure that sufficient quantities of the Products are available for Commercialization on and after BERTEK's receipt of FDA approved, saleable Products from AMIDE. As soon as is reasonably practical, but in no case later than thirty (30) days after ANDA approval, BERTEK shall provide AMIDE with purchase orders setting forth BERTEK's requirements for the Products to be sold during the first ninety (90) days of the Product Launch (the "Launch Projection"). Thereafter, but in no case later than ninety (90) days after ANDA approval, BERTEK shall provide AMIDE with its second ninety (90) day projection ("2nd Projection") for Products. AMIDE shall manufacture one hundred percent (100%) of both BERTEK's Launch Projection and 2nd Projection.
- (b) As soon as BERTEK can establish a buying pattern, but in no event later than ninety (90) days after the approval of the ANDA, BERTEK shall provide AMIDE by the fifteenth (15th) day of every month thereafter for the term of this Agreement with a twelve (12) month rolling forecast setting forth BERTEK's best estimate of its requirements of the Products.
- (c) BERTEK shall be required to submit purchase orders equal to and AMIDE shall be required to produce and supply not less than seventy-five percent (75%) and not

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more than one hundred twenty-five percent (125%) of the quantities set forth in purchase orders for any and all Product after the Launch Projection and 2nd Projection. AMIDE shall use its Commercially Reasonable Efforts, but is not required, to accommodate any increase in the quantity of the Products that BERTEK shall request under new purchase orders.

- 3.2 In the event of a sudden and unexpected material increase or decrease in the demand for the Products in the marketplace, the Parties shall negotiate in good faith the terms and conditions of any requested increase or decrease by BERTEK in the quantities of Products set forth in BERTEK's most recent purchase orders and its forecasts of its estimated requirements. For the purposes of this section, a material increase or decrease shall be any change in a particular month's quantity of Product of more than ten percent (10%).
- 3.3 AMIDE shall not be deemed to be in violation of this Agreement if it cannot obtain Raw Material in sufficient quantities to meet BERTEK's Launch Projection or other purchase orders provided AMIDE has ordered sufficient amounts of Raw Materials to meet BERTEK's Launch Projections, 2nd Projection and other purchase orders.

IV. PAYMENTS AND REPORTS

- 4.1 (a) BERTEK shall pay AMIDE the Transfer Price as set forth in Exhibit B for shipments of Products sent by AMIDE to BERTEK, within thirty (30) days from the date of receipt of such Products by BERTEK. Each shipment shall be accompanied by a certificate of analysis ("COA") and a packing list and shall be followed within three (3) business days by an invoice which shall reflect the Transfer Price on the date of shipment by AMIDE for each order of the Products:

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- (b) BERTEK shall remit payment of the Residual Due (as hereinafter defined) within forty-five (45) days after the end of a Calendar Quarter.
- (c) BERTEK shall keep such records as are accurate to determine the payments due AMIDE. Such records shall be retained by BERTEK and shall be made available for reasonable review or audit upon reasonable notice of at least ten (10) business days, at AMIDE's request and expense, by a representative appointed by AMIDE for the purpose of verifying BERTEK's calculation of Residual Due hereunder and of determining the correctness of such calculation and the payments due AMIDE. Such records shall be retained for three (3) years from the date of their origin, or one (1) year after the date of termination of this Agreement, whichever occurs first, but need not be retained more than three (3) years from the date of their origin or more than one (1) year after the date of the termination of this Agreement, whichever is appropriate, or as otherwise required by law. If AMIDE requests an audit, such records shall be retained for one (1) year but need not be retained more than one (1) year after the completion of any audit thereof requested by AMIDE.

4.2 In addition to the Transfer Price, BERTEK shall pay AMIDE thirty five (35%) percent of BERTEK's Gross Margin on the Products. The calculation of Gross Margin and AMIDE's thirty five (35%) percent of the Gross Margin (hereinafter the "Residual Due") shall be paid to AMIDE within forty-five (45) days after the end of a Calendar Quarter. A summary of the calculation of the Residual Due to AMIDE will include Gross Sales of the Products less a summary by category of all returns, credits, rebates, allowances and other debits and credits relevant to the calculation of Gross Margin, actually granted to

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customers during the period to which the payment relates, or any prior period to the extent not previously accounted for. Exhibit C, attached hereto, shows an example of the above calculation for illustration purposes only.

- 4.3 The Manufacturing Cost will be adjusted when AMIDE's Raw Material cost varies by more than ten percent (10%) from the cost currently used in the calculation of the Manufacturing Cost. AMIDE will notify BERTEK of any change in the Manufacturing Cost, the reason for such change, and provide documentation reflecting such change.
- 4.4 Notwithstanding section 4.3 hereof AMIDE reserves the right on reasonable notice to BERTEK to adjust Manufacturing Costs once every twelve (12) months based on changes to any and all labor, excipients, Raw Material and related component and packaging costs for Products.
- 4.5 All payments required to be made to AMIDE under this Agreement shall be made in United States dollars and may be made by either wire or paper transfer on the due date to the following address:

Amide Pharmaceutical, Inc.
101 East Main Street
Little Falls, New Jersey 07424
Attention: ACCOUNTS RECEIVABLE

or to any other address that AMIDE may advise in writing.

V. SHIPPING

- 5.1 All shipments of Products from AMIDE to BERTEK will be shipped to the destination specified by BERTEK and will be in accordance with the reasonable instructions for shipping and packing set forth in the relevant BERTEK purchase order. Delivery shall be made F.O.B. Destination. Title and risk of loss or damage to the Products shall remain

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with AMIDE until Products are delivered by AMIDE to the destination specified by BERTEK in its purchase order.

VI. PRODUCTS TESTING/INSPECTION; MANUFACTURING

6.1 BERTEK and AMIDE agree to establish standard operating procedures in accordance with the FFDCA and other FDA rules and regulations for the final release of the Products manufactured by AMIDE. Upon reasonable notice by BERTEK to AMIDE, AMIDE shall make available at AMIDE's offices lot history records, testing results, and other documentation created by AMIDE during its usual and customary manufacturing processes, as may be reasonably requested by BERTEK to document compliance with the release specifications, or for quality control or quality assurance purposes.

6.2 AMIDE shall perform quality assurance testing with respect to the Products sold hereunder, including stability testing, so that the Products conform with the Specifications.

AMIDE shall provide the results thereof to BERTEK in the form of a Certificate of Analysis (hereinafter "COA"). AMIDE will also assist BERTEK to produce Material Safety Data Sheets (hereinafter "MSDS") as required for the Products, and updates of same as necessary. BERTEK will permit AMIDE's personnel, upon reasonable notice, to visit at reasonable intervals, and for reasonable durations during regular business hours, any BERTEK facility used for the storage, packaging and distribution of the Products and will allow such personnel to review any relevant records in connection therewith.

AMIDE will permit BERTEK's personnel, upon reasonable notice of at least ten (10) days, to visit at reasonable intervals, and for reasonable durations during regular business hours, any AMIDE facility used for the manufacture, packaging or storage of the Products and

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will allow such personnel to review any relevant records in connection therewith.

- 6.3 BERTEK shall have a period of thirty (30) days from the later of (a) the date of BERTEK's receipt of the Products at the BERTEK facility designated in the purchase order, or (b) the date of BERTEK's receipt of the COA's applicable to such Products, to inspect any shipment of Products to determine whether such shipment conforms to the Specifications.

If BERTEK determines that the Products do not conform to the Specifications, it shall notify AMIDE in writing within forty-eight (48) hours of discovery and identify the alleged non-conformity (hereinafter, "Alleged Non-Conforming Products"). BERTEK's failure to notify AMIDE within the stipulated period will be deemed, for purposes of this Agreement, as BERTEK's acceptance of such shipment and shall constitute a waiver of any claims BERTEK may have against AMIDE with respect to such shipment subject, however, to BERTEK's right to reject Products for latent defects discovered by BERTEK or BERTEK's customer(s) after such stipulated period has expired, and also subject to claims for any Product which is the subject of a recall. BERTEK shall quarantine the Alleged Non-Conforming Products and AMIDE will have thirty (30) business days to examine such Alleged Non-Conforming Products. BERTEK shall thereafter return the Alleged Non-Conforming Products to AMIDE, at a location designated by AMIDE and at AMIDE's expense ("Return Costs"), unless at some point thereafter the Alleged Non-Conforming Products are determined to be conforming to Specifications pursuant to the procedures set forth hereinbelow, in which case the Return Costs shall be paid by BERTEK or credited to AMIDE if AMIDE has already paid the Return Costs. AMIDE shall use its Commercially Reasonable Efforts to replace any Alleged Non-Conforming

Products within the shortest possible time. BERTEK shall have no responsibility to AMIDE for the Transfer Prices of non-conforming Products but shall pay AMIDE the Transfer Prices for the replacement Products.

- 6.4 (a) In the event AMIDE does not agree with BERTEK's determination that the Products fail to meet Specifications, the Parties shall, in good faith, attempt to resolve such dispute. In the event the Parties cannot resolve said dispute among themselves they shall submit the matter to an independent third party testing laboratory agreeable to both BERTEK and AMIDE for a binding determination, which determination shall be non-appealable by the Parties (the "Final Determination"). The expenses of obtaining the determination shall be paid by the Party whose determination as to the Products was incorrect. If either Party cannot agree to an independent third party testing laboratory the Parties shall each submit three independent laboratories to Lachman Consultant Group of Westbury, New York for the selection of such independent third party laboratory.
- (b) In the event the Final Determination proves the allegedly non-conforming Products are conforming and BERTEK elects not to sell such Products such election shall be made with written notice to AMIDE of such election within ten (10) days after the Final Determination. BERTEK shall pay AMIDE three (3) times the Transfer Price of all rejected Product which BERTEK elects not to sell.
- 6.5 AMIDE will manufacture, package, label, store, and ship the Products in accordance with Specifications set forth in the ANDA and as such ANDA may be amended from time to time. BERTEK shall be promptly and fully advised of any new instructions or

specifications required by the FDA or the FFDCA. BERTEK's Quality Control personnel, upon reasonable prior notice to AMIDE, shall be permitted to observe the manufacture of Products being manufactured by AMIDE for BERTEK. In the event that AMIDE cannot manufacture Products in accordance with instructions and Specifications, AMIDE shall promptly so advise BERTEK. AMIDE shall not change any ANDA or Specification without the prior written consent of BERTEK.

- 6.6 AMIDE will package and label the Products under the BERTEK name and AMIDE shall provide all finished labeling for the Products in accordance with any applicable FDA or other regulatory labeling requirements. With the exception of FDA requirements, BERTEK shall have sole discretion over the format and content of the labeling, and shall provide AMIDE with artwork for such labeling. AMIDE shall be responsible for any required reporting to the FDA or required approvals from the FDA related to the use of the BERTEK name on the labeling.

- 6.7 (a) BERTEK and AMIDE agree that it is their intent that AMIDE shall be the manufacturer of Products and that BERTEK or an Affiliate of BERTEK be designated the "Primary Alternate Manufacturers", assuming BERTEK or an affiliate of BERTEK is able to qualify as a manufacturer of Product under FDA rules and regulations ("Qualification"). AMIDE may in its sole and exclusive discretion and at its sole and exclusive costs simultaneously select other alternate manufacturers for the manufacture of Products (hereinafter "Secondary Manufacturers"). However, a Secondary Manufacturer shall only be permitted to manufacture Products in the event that Primary Manufacturer is unable to obtain

Qualification or Primary Manufacturer otherwise is unable or unwilling to manufacture Product.

- (b) Within a reasonable period of time following approval of the ANDA, BERTEK and AMIDE agree to begin the process of qualifying BERTEK as the Primary Alternate Manufacturer under the ANDA. AMIDE will be responsible for making any necessary regulatory filings, and BERTEK will provide AMIDE with such reasonable assistance which may be necessary in order to obtain FDA approval. AMIDE agrees to diligently pursue the designation of BERTEK or an Affiliate of BERTEK, as an alternate manufacturing site, and will keep BERTEK apprised of the status of same. BERTEK shall use its Commercially Reasonable Efforts to obtain Qualification.
- (c) In the event AMIDE is willing but unable to Manufacture Product due to circumstances, beyond its control, including by way of example and not limitation, a Force Majeure event or unavailability of Raw Material except as set forth in 3.3 hereof (hereinafter "Scenario A"), then in such event, assuming BERTEK has been certified by the FDA as an alternative manufacturer of products, BERTEK shall have the sole and exclusive right to manufacture Products. Notwithstanding Scenario A, BERTEK shall continue to pay AMIDE the Residual Due through the end of the Scenario A event or twelve (12) months, whichever is shorter. Thereafter BERTEK shall pay AMIDE the Reduced Residual Due on any and all Product sold by BERTEK through the termination of expiration of this Agreement, or the extensions hereof, whichever event occurs last. At any time during the first

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twelve (12) months of AMIDE's inability to manufacture Product (the "12 Month Period") AMIDE is able to manufacture Products, AMIDE shall commence manufacturing Products and BERTEK shall cease manufacturing Products. After the "12 Month Period" and in the event AMIDE is able or reasonably anticipates it will be able to manufacture Products within ten (10) months, AMIDE shall give ten (10) months written notice of AMIDE's intent to begin manufacturing Products again. Upon the expiration of the ten (10) month notice period, unless sooner agreed to by BERTEK and AMIDE, AMIDE shall recommence manufacturing Products and BERTEK shall cease manufacturing Products, and the terms of this Agreement shall continue in full force and effect. If AMIDE commences manufacture of the Products pursuant to this 6.7(c), AMIDE must purchase from BERTEK, at BERTEK's cost, all Raw Materials and components that were purchased by BERTEK for use in the Manufacture of the Products.

- (d) In the event BERTEK or its Affiliate has not obtained Qualification and AMIDE has designated and obtained Qualification for a Secondary Alternate Manufacturer such Secondary Alternate Manufacturer shall immediately commence and continue manufacturing Products for BERTEK until Scenario A is over and AMIDE is able to manufacture Product. During this Scenario A event and so long as a Secondary Alternate Manufacturer other than BERTEK or its Affiliate is manufacturing Product, BERTEK shall pay AMIDE the Residual Due.
- (e) In the event AMIDE elects for any reason whatever (excluding Scenario A) to not manufacture Products for BERTEK ("Scenario B"), assuming BERTEK shall have

been authorized by the FDA to manufacture Product, BERTEK shall have the sole and exclusive right to manufacture Products solely for the purposes set forth herein. BERTEK shall pay AMIDE the Reduced Residual Due on the sale of any and all Product by BERTEK through the termination or expiration of this Agreement or any renewals hereof, whichever occurs last.

- (f) During Scenario B, BERTEK shall pay AMIDE the Reduced Residual Due of ten (10%) percent and BERTEK shall make all such Reduced Residual Due Payments within forty five (45) days after the end of each Calendar Quarter.

VII. REGULATORY ISSUES, MEDICAL INQUIRY AND RECALL

- 7.1 (a) AMIDE shall remain responsible for maintaining and fulfilling all regulatory requirements in the Territory with respect to the manufacture of Products that are imposed by Law upon AMIDE as the manufacturer of the Products and the holder of the ANDA in connection therewith. BERTEK shall be responsible for obtaining, maintaining and fulfilling all regulatory requirements in the Territory with respect to the Products that are imposed by Law upon BERTEK in connection with BERTEK's marketing, distribution and sale of the Products. Each Party will, on a timely basis, provide the other Party with all information that is reasonably necessary and relevant to assist such Party in fulfilling its regulatory obligations.
- (b) BERTEK and AMIDE shall cooperate in the reporting of adverse drug experience information and other post marketing reports as are required to be filed with the FDA or its equivalent. BERTEK shall refer or submit to AMIDE all adverse drug experience reports and other medical inquiries or quality complaints associated

with the Products within forty-eight (48) hours of BERTEK's receipt of such reports. All telephone calls received shall be referred to AMIDE. AMIDE will be responsible for fulfilling any regulatory requirements with respect to such events, including but not limited to the filing of all Form FD 2253's, contact and follow-up with the patient or reporter of the event, and will make any necessary contact with the FDA regarding the subject matter of same.

7.2 AMIDE shall be responsible for filing and maintaining all documentation and other information as required by each and every state and locality (hereinafter "State") for the purpose of listing the Products on each such State's formulary or other similar authority, and for obtaining such other approvals as may be necessary to sell the Products in the Territory. BERTEK shall provide AMIDE with such assistance as reasonably necessary to obtain such listings. AMIDE shall designate BERTEK its authorized representative solely for the purpose to obtain authorization for Product listing on each State's formulary or other State Authority at BERTEK's sole cost and expense. BERTEK shall permit and AMIDE shall be allowed to assist in and attend State formulary or other State Authority meetings. BERTEK shall indemnify AMIDE for any and all claims arising from any BERTEK statements or representation made to such State's formulary or other State Authorities.

7.3 In the event BERTEK or AMIDE shall be required or requested by any governmental authority (or shall voluntarily decide) to recall any Products because such Products may violate any Laws or for any other reason, the Parties shall cooperate fully with one another in connection with any recall. If a recall is due to AMIDE's negligence, willful misconduct

or breach of this Agreement, AMIDE shall reimburse BERTEK for the Transfer Prices paid by BERTEK for such recalled Products, any monies paid to AMIDE from the Residual Due, Reduced Residual Due and all of the reasonable costs and expenses actually incurred by BERTEK in connection with the recall including, but not limited to, costs of retrieving Products already delivered to customers, costs and expenses BERTEK is required to pay for notification, shipping and handling charges, and such other costs as may be reasonably related to the recall. If a recall is due to BERTEK's negligence, willful misconduct or breach of this Agreement, BERTEK shall remain responsible for the Transfer Prices for such recalled Products and shall reimburse AMIDE for all the reasonable costs and expenses described above actually incurred by AMIDE in connection with such recall including administration of the recall and such other actual costs as may be reasonably related to the recall. If a recall results from a cause other than the negligence, willful misconduct or breach of this Agreement of or by BERTEK or AMIDE, the Parties shall share equally, all of the costs of the recall, including the Transfer Price. Prior to any reimbursements pursuant to this Section, the Party claiming any reimbursement shall provide the other Party with reasonably acceptable documentation of all reimbursable costs and expenses.

- 7.4 Notwithstanding anything to the contrary set forth in this Agreement, BERTEK shall have the right, without AMIDE's prior approval, and in accordance with any and all FDA requirements to promote and publicize the Products in its customary fashion, and may publicize such information about the Products as it usually and customarily provides for its own Products utilizing its usual and customary channels of communication, and its

standard forms, which may be revised from time to time ("Marketing and Promotion Information") BERTEK agrees to provide AMIDE within a reasonable period of time, copies of any and all Marketing and Promotion Information. AMIDE shall not distribute any promotional materials that relate to BERTEK or its products without the prior written consent of BERTEK.

VIII. TERM AND TERMINATION

- 8.1 (a) The initial term of this Agreement shall begin on the Commencement Date and shall end ten (10) years after the date of the FDA approval of AMIDE'S ANDA. BERTEK may renew for a two (2) year extended term upon written notice to AMIDE not more than ninety (90) days prior to the end of the initial term. Thereafter the Agreement shall automatically renew at the end of any extended term for additional two (2) year extensions unless BERTEK provides AMIDE with written notification not more than ninety (90) days prior to the end of any such extended term of its intention not to renew.
- (b) In the event that AMIDE elects to not manufacture Product as provided for herein, or this Agreement terminates pursuant to Section 8.2(b), assuming BERTEK has been authorized by the FDA to manufacture Products, BERTEK shall have the right to manufacture the Products under AMIDE'S ANDA, as set forth in Section 6.7 through the balance of the initial term and the renewals thereof and BERTEK shall pay AMIDE during such time the Reduced Residual Due on any and all Products.
- (c) At any time during this Agreement or any renewals hereof BERTEK elects not to

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renew this Agreement, AMIDE may request and BERTEK shall transfer the Trademark(s) used by BERTEK during this Agreement and pursuant to the terms of the Trademark License Agreement attached hereto as Exhibit E.

- 8.2 (a) If either Party shall at any time materially fail to abide by or fail to perform in accordance with any of the material provisions of this Agreement, the other Party shall have the right to terminate this Agreement upon forty-five (45) days' written notice to the allegedly defaulting Party specifying the default complained of (the "Default"), setting forth the underlying reasons for its belief regarding the Default and the remedy the non-defaulting Party demands. The Party allegedly in default may cure the asserted breach or commence litigation pursuant to Article XV within the notice period; provided, however, that before a Party shall commence a lawsuit, the Parties shall meet and in good faith attempt to resolve the dispute. If litigation is commenced, the Agreement shall continue in full force and effect as if the alleged breach had not occurred, pending the outcome of such litigation, unless the Default is relating to a breach by BERTEK of sections 4.1(a), 4.1(b), 11.2(e) or 11.2(f), in which case AMIDE shall have the right to discontinue the manufacture and supply of Products to BERTEK.
- (b) If either Party (i) institutes or has instituted against it any insolvency, receivership, Chapter 7 bankruptcy or other proceedings for the settlement of that Party's debts, and such proceedings are not dismissed within sixty (60) days, (ii) makes an assignment for the benefit of creditors, or (iii) dissolves or ceases to do business, the other Party may terminate this Agreement without notice.

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(c) In the event that AMIDE on more than one (1) instance within a twelve (12) month period fails to manufacture Products within sixty (60) days after such Products are ordered, and AMIDE's failure is not attributable to non-availability of Raw Material or a Force Majeure Event then AMIDE immediately shall cure or transfer the manufacture of Product to the Primary Alternate Manufacturer facility under AMIDE'S ANDA. With the limited exception of the unavailability of Raw Material, while any issue is awaiting determination by Court proceedings, BERTEK shall not be without its required supply of Products.

8.3 Termination of this Agreement for any reason shall be without prejudice to:

- (a) AMIDE's right to receive all payments due from BERTEK, including by way of example and not limitation, Transfer Prices, Residual Due and Reduced Residual Due, as of the last receipt of any sale proceeds from Products by BERTEK;
- (b) BERTEK's right to receive all payments due from AMIDE as of the effective date of such termination;
- (c) BERTEK's right to sell such Products remaining in its inventory and at BERTEK's option, BERTEK may elect to sell Products for which purchase orders have been submitted to AMIDE; and
- (d) Any other legal, equitable, or administrative remedies as to which either Party is or may become entitled.

8.4 In the event of a breach by BERTEK under Sections 4.1(a), 4.1(b), 4.2 and 11.2(f), and after receipt of the required notice of breach from AMIDE, which alleged breach BERTEK fails to cure within the time period and conditions set forth in Section 8.2(a), BERTEK shall immediately undertake any and all actions necessary at BERTEK's sole cost and

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expense, to transfer any and all Trademark name(s) used by BERTEK for sale of Products by BERTEK.

8.5 (a) After six months from the date of the execution of this Agreement and thereafter until such time as AMIDE receives approval of the ANDA which must contain an AB Rating to the referenced product Lanoxin®, BERTEK may elect, in its sole discretion, to terminate this Agreement, regardless of the cause for such failure of AMIDE to obtain approval. BERTEK shall advise AMIDE of its election to terminate this Agreement pursuant to this section upon thirty (30) days written notice to AMIDE. This Termination provision shall cease and become of no further effect upon AMIDE's approval as set forth in Section 8.5(a).

(b) Notwithstanding anything to the contrary set forth in this Agreement, in the event BERTEK terminates this Agreement pursuant to Section 8.5(a), it shall not be prevented from developing or otherwise acquiring a digoxin product for manufacture, use and sale both in and outside the Territory. Further, in the event of a termination pursuant to 8.5(a) hereof, BERTEK shall have no obligation to grant to AMIDE any right to the Trademark(s), and AMIDE specifically acknowledges it shall not be entitled to such Trademark(s).

IX. INDEMNIFICATION, INSURANCE AND TRADEMARK

9.1 BERTEK agrees to indemnify, defend and hold AMIDE harmless from and against any Losses resulting from or arising out of BERTEK's storage, handling, marketing, promotion, distribution, commercialization, and/or delivery of the Products; the execution by BERTEK of this Agreement, the performance or breach by BERTEK of its

representations, warranties or obligations under this Agreement or the negligence or willful misconduct of BERTEK, its employees or its agents (collectively "BERTEK Activities"), except to the extent such Losses result from AMIDE Activities (as defined in Section 9.2).

9.2 AMIDE agrees to indemnify, defend and hold BERTEK harmless from and against any Losses resulting from or arising out of AMIDE's design, manufacturing, testing, packaging, storing, handling, and labeling of the Products, the execution by AMIDE of this Agreement, the performance or breach by AMIDE of its representations, warranties or obligations under this Agreement, (including but not limited to, claims that the sale of the Products in the Territory infringes the Intellectual Property rights of a third party) or the negligence or willful misconduct of AMIDE, its employees or its agents (collectively "AMIDE Activities"), except to the extent such Losses result from BERTEK Activities (as defined in Section 9.1).

9.3 A Party seeking indemnification ("Indemnified Party") shall notify, in writing, the other Party ("Indemnifying Party") within fifteen (15) days of the assertion of any claim or discovery of any fact upon which the Indemnified Party intends to base a claim for indemnification. An Indemnified Party's failure to so notify the Indemnifying Party shall not, however, relieve such Indemnifying Party from any liability under this Agreement to the Indemnified Party with respect to such claim except to the extent that such Indemnifying Party is actually denied, during the period of delay in notice, the opportunity to remedy or otherwise mitigate the event or activity(ies) giving rise to the claim for indemnification and thereby suffers or otherwise incurs additional liquidated or other

readily quantifiable damages as a result of such failure. The Indemnifying Party, while reserving the right to contest its obligations to indemnify hereunder, shall be responsible for the defense of any claim, demand, lawsuit or other proceeding in connection with which the Indemnified Party claims indemnification hereunder. The Indemnified Party shall have the right at its own expense to participate jointly with the Indemnifying Party in the defense of any such claim, demand, lawsuit or other proceeding, but with respect to any issue involved in such claim, demand, lawsuit or other proceeding with respect to which the Indemnifying Party has acknowledged its obligation to indemnify the Indemnified Party hereunder, the Indemnifying Party shall have the right to select counsel, settle, try or otherwise dispose of or handle such claim, demand, lawsuit or other proceeding on such terms as the Indemnifying Party shall deem appropriate, subject to prior written approval of the Indemnified Party, which shall not be unreasonably withheld.

- 9.4 Insurance. Each Party shall, throughout the term of this Agreement, obtain and maintain at its own cost and expense from a qualified insurance company, comprehensive general liability insurance, including standard Products liability insurance designating the other Party as an additional insured. Such policy shall provide protection against any and all claims, demands and causes of action arising out of any defects, alleged or otherwise, of the Products or any material used in connection therewith or any use thereof. The amount of coverage shall be a minimum of Five Million Dollars (\$5,000,000.00) combined single limit coverage, for each occurrence for bodily injury and/or for property damage. Each Party agrees to furnish the other Party a certificate of insurance evidencing such insurance upon request and the insured Party shall not at any time manufacture, offer for sale, sell,

ship or distribute Products or otherwise act pursuant to this Agreement unless such insurance is in effect.

- 9.5 Trademark. AMIDE acknowledges that BERTEK will market and promote the Products under a trademark, to be selected and owned by BERTEK ("Trademark"). BERTEK shall be responsible for obtaining and maintaining such Trademark registration. AMIDE shall not use the Trademark or any mark confusingly similar, except in the manner authorized by BERTEK. AMIDE acknowledges and agrees that nothing in this Agreement is intended to, nor shall it, convey any rights in such Trademark to AMIDE, either in the Territory or elsewhere.

X. CONFIDENTIAL INFORMATION

- 10.1 Confidential Information is defined by and subject to the provisions of that Secrecy Agreement ("S.A.") entered into between Mylan Pharmaceuticals, Inc. and AMIDE on December 15, 1997, which is incorporated herein by reference and attached hereto as Exhibit E, and which shall be amended as follows:

- (a) The Parties of the Confidential Agreement shall be amended to include BERTEK Pharmaceuticals, Inc. and its Affiliates as defined in the Agreement and not the S.A. and Mylan Laboratories, Inc.;
- (b) The term of the S.A. shall run from December 15, 1997 through the expiration or termination of this Agreement plus five (5) years from the latest date on which information (as defined in the S.A.) is disclosed to the other Parties.
- (c) The Governing Law provision in Section XIV shall be eliminated and the provisions in the Agreement shall control.

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Neither BERTEK nor AMIDE shall issue any press release or public announcement with respect to the Agreement without the prior consent of the other as to the form and content of such release, except as such release or announcement may be required by Law.

- 10.2 If either Party determines that a release of information concerning this Agreement is required by Law, it shall notify the other in writing at least ten (10) days (or such shorter period where legally required) before the time of the proposed release. Such notice shall include the exact text of the proposed release and the time and manner of the release. At the other Party's request, and before the release, the Party desiring to release further information shall consult with the other Party on the necessity for the disclosure and the text of the proposed further disclosure. In no event shall a release include more information regarding the existence or terms of this Agreement than is required by Law. BERTEK and AMIDE recognize that in addition to the other exceptions set forth herein, disclosure of this Agreement to IRS and other tax authorities is likely to be required, and BERTEK and AMIDE each waives the requirements of this subsection with respect to disclosure to such entities.

XI. REPRESENTATIONS AND WARRANTIES

- 11.1 Representations and Warranties by AMIDE. AMIDE hereby represents and warrants to BERTEK as follows:
- (a) AMIDE is a corporation duly organized and validly existing under the laws of the State of New Jersey;
 - (b) AMIDE has the requisite corporate authority to execute and deliver this agreement and to perform its obligations hereunder;

- (c) Any Products delivered by AMIDE to BERTEK shall, at the time of shipment have been manufactured, packaged, stored and shipped by AMIDE in conformity with CGMPs, Specifications, and any other applicable Laws, and shall not be adulterated, misbranded or otherwise violative of the FFDCA or other applicable Laws;
- (d) With the exception of AMIDE's current customer Kaiser Permanente, the execution and performance of AMIDE's obligations hereunder, are not and will not be in violation of or in conflict with any obligation, contract or agreement it may have with any third party, including but not limited to Duramed Pharmaceuticals Inc.;
- (e) AMIDE is not debarred and AMIDE has not and will not use in any capacity the services of any person debarred under subsection 306(a) or (b) of the Generic Drug Enforcement Act of 1992. If at any time this representation and warranty is no longer accurate, AMIDE shall immediately notify BERTEK of such fact;
- (f) AMIDE has and will maintain throughout the term of this Agreement all permits, licenses, registrations and other forms of governmental authorization and approval as required by Law in order for AMIDE to execute and deliver this Agreement and to perform its obligations hereunder in accordance with all applicable Laws;
- (g) To the best of AMIDE's knowledge and belief, there are no investigations, adverse third party allegations or actions, or claims against AMIDE, including any pending or threatened action against AMIDE in any court or by or before any governmental body or agency, with respect to the Products, or its obligations set forth herein

which may materially adversely affect AMIDE's ability to perform its obligations under this Agreement, except as to a certain FDA Consent Decree dated March 25, 1992, a copy of which has been furnished to Bertek and which Bertek acknowledges receipt; and

- (h) To the best of AMIDE's knowledge, the manufacture, use or sale of the Products in the Territory will not infringe the Intellectual Property rights of any third party.

11.2 Representations and Warranties by BERTEK. BERTEK hereby represents and warrants to AMIDE as follows:

- (a) BERTEK is a corporation duly organized and in good standing under the laws of the State of Texas;
- (b) BERTEK has the requisite corporate authority to execute and deliver this Agreement and to perform its obligations hereunder;
- (c) The execution and performance of BERTEK's obligations hereunder, are not and will not be in violation of or in conflict with any obligations, contracts or agreements it may have with any third party;
- (d) BERTEK is not debarred and BERTEK has not and will not use in any capacity the services of any person debarred under subsections 306(a) or (b) of the Generic Drug Enforcement Act of 1992. If at any time this representation and warranty is no longer accurate, BERTEK shall immediately notify AMIDE of such fact; and
- (e) BERTEK has and will maintain throughout the term of this Agreement all federal, state and local permits, licenses, registrations and other forms of governmental authorization and approval as required by Law in order for BERTEK to execute

and deliver this Agreement and to perform its obligations hereunder in accordance with all applicable Laws.

- (f) BERTEK shall not during the terms of this Agreement and any renewals hereof and for a period of not less than two (2) years after the termination, non-renewal or natural expiration of this Agreement, file an ANDA for digoxin.
- (g) BERTEK shall not during the term of this Agreement and any renewals thereof and for a period of not less than two years after the termination, non-renewal or natural expiration, pursue the development of, develop, or create an ANDA for Products, or manufacture, distribute, sell, advertise for sale Products outside of the Territory.
- (h) BERTEK shall share equally in any and all costs and expenses including attorneys fees, and may join in the defense of any actions or intellectual property claims arising from the tradenames selected for the Product and brought by a manufacturer, creator or developer.

11.3 BERTEK and AMIDE, in performing their obligations hereunder shall materially comply with all applicable Laws. In the event AMIDE receives notice of an inspection or other notification by a governmental entity, including FDA, relating to the Products, promotional materials or other matters within the scope of this Agreement, AMIDE shall notify BERTEK on the same day such notice or notification is received, and provide to BERTEK, within seventy-two (72) hours, copies of all relevant documents, including FDA Forms 482, 483 warning letters and other correspondence and notifications relating to Products, as BERTEK may reasonably request. BERTEK and AMIDE agree to cooperate with each other during any inspection, investigation or other inquiry by FDA or any other

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governmental entity, including providing information and/or documentation, as requested by FDA or other governmental entity. AMIDE and BERTEK also agree to discuss any response to observations or notifications received and to give the other Party an opportunity to comment on any proposed response before it is made. In the event of disagreement concerning the form or content of such response, however, AMIDE shall be responsible for deciding the appropriate form and content of any response with respect to any of its cited activities and BERTEK shall be responsible for deciding the appropriate form and content of any response with respect to any of its cited activities.

XII. NOTICES

12.1 Any notices or reports required or permitted under this Agreement shall be deemed to have been given for all purposes if mailed by first class certified or registered mail or transmitted electronically by facsimile with mailed confirmation copy to the following address of either Party:

For BERTEK: BERTEK Pharmaceuticals Inc.
781 Chestnut Ridge Road
Morgantown, WV 26505
Attn: William W. Richardson
President

For AMIDE: Amide Pharmaceutical, Inc.
101 East Main Street
Little Falls, New Jersey 07424
Attn: Chandu Patel
President and CEO

or to such other addresses as shall have been subsequently furnished by written notice to the other Party.

XIII. GOVERNING LAW AND PARTIES BOUND

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- 13.1 Parties Bound. This Agreement shall be binding upon and inure to the benefit of the Parties and their successors and assigns. This Agreement and the rights granted herein may not be assigned by either Party without the prior written consent of the other Party except to a successor or assignee of all or substantially all of one party's business or assets.

XIV. FORCE MAJEURE

- 14.1 If either Party is prevented from complying, either totally or in part, with any of the terms or provisions set forth herein, by reason of Force Majeure, including, by way of example and not of limitation, fire, flood, explosion, storm, strike, lockout or other labor dispute, riot, war, rebellion, accidents, acts of God, acts of governmental agencies or instrumentalities (including, but not limited to, lack of a sufficient governmentally-mandated quota of the Products) or any other cause or externally induced casualty beyond its reasonable control, whether similar to the foregoing contingencies or not, said Party shall provide written notice of same to the other Party. Said notice shall be provided within five (5) business days of the occurrence of such event and shall identify the requirements of this Agreement or such of its obligations as may be affected and to the extent so affected, said obligations shall be suspended during the period of such disability. The Party prevented from performing hereunder shall use Commercially Reasonable Efforts to remove such disability, and shall continue performance whenever such causes are removed. The Party so affected shall give to the other Party a good faith estimate of the continuing effect of the Force Majeure condition and the duration of the affected Party's nonperformance. Upon BERTEK's receipt of the notice of AMIDE pursuant to this Article, BERTEK may elect to manufacture Products as provided herein and as otherwise

set forth in paragraph 6.7(c).

XV. NO ORAL MODIFICATIONS

15.1 No change, modification, amendment or waiver of any obligation, term or provision contained herein shall be valid or enforceable unless same is reduced to writing and signed by a duly authorized representative of each of the Parties to be bound hereby.

XVI. INDEPENDENT CONTRACTORS

16.1 This Agreement shall not constitute or give rise to any employer-employee, agency, partnership or joint venture relationship among or between the Parties, and each Party's performance hereunder is that of a separate, independent entity.

XVII. NO IMPLIED RIGHTS

17.1 Nothing in this Agreement shall be deemed or implied to be the grant by one Party to the other of any right, title or interest in the Products, Intellectual Property or any other proprietary right of the other except as is expressly provided for herein.

XVIII. SEVERABILITY

18.1 To the extent any provision or term set forth herein is or becomes unenforceable by operation of Law, such unenforceability shall not affect the remaining provisions of this Agreement. The Parties agree to renegotiate in good faith any provision or term held to be unenforceable and to be bound by the mutually agreed substitute provision.

XIX. MODIFICATION BY OPERATION OF LAW

19.1 If any of the terms or provisions of this Agreement are in or come into conflict with any applicable Law within the Territory, then such term or provision shall be deemed inoperative to the extent it may conflict therewith and shall be deemed to be modified to

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conform with such Law unless such modification would render the affected provision inconsistent with or contrary to the intent of the Parties. However, in the event the terms and conditions of this Agreement are materially altered as a result of this subsection, the Parties shall in good faith attempt to renegotiate said terms and conditions to resolve any disputes related thereto. Should they be unable to agree on suitable substitute language, the issue shall be referred to arbitration pursuant to Article XV.

XX. CAPTIONS

20.1 Article and section headings are provided for convenience only and are not to be used in construing the intent of the Parties.

XXI. SURVIVORSHIP

21.1 The provisions of Sections 2.4, IV, 6.1, 6.2, 6.3, 6.4, VII, IX, X, XI, XII, XIII, XV survive any expiration or termination of this Agreement.

XXII. ENTIRE AGREEMENT

22.1 This instrument, including the Secrecy Agreement and the Exhibits attached hereto, contains the entire agreement between the Parties and supersedes all prior drafts or understandings.

XXIII. WAIVER

23.1 The waiver by either Party to this Agreement of a breach of any provision set forth herein or of any right contained herein shall not operate as or be construed as a continuing waiver or a waiver of any subsequent breach or right granted herein.

XXIV. SINGULAR AND PLURAL

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24.1 The singular form of any noun or pronoun shall include the plural when the context in which such a word is used is such that it is apparent the singular is intended to include the plural or vice versa.

XXV. COUNTERPARTS

25.1 This Agreement may be executed in two (2) counterparts each of which is to be considered an original and taken together as one and the same document.

XXVI. DOCUMENT PREPARATION

26.1 The Parties acknowledge that this Agreement is a product of negotiations and that no inference should be drawn regarding the drafting or preparation of this document.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed in duplicate by their duly authorized representatives in the places provided below:

BERTEK PHARMACEUTICALS INC.

By

Title President and CEO

Date August 5, 1999

AMIDE PHARMACEUTICAL, INC.

By

Title PRESIDENT

Date 8/5/99

MYLAN LABORATORIES INC.

By

Title Senior Vice President

Date August 5, 1999

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EXHIBIT A

PRODUCTS

| <u>Product Name</u> | <u>Strength</u> | <u>Bottle Size</u> | <u>NDC No.</u> |
|----------------------------|------------------------|---------------------------|-----------------------|
| Digoxin Tablets, USP | 0.125mg | 100 | 62794-145-01 |
| | | 1,000 | 62794-145-10 |
| | | 5,000 | 62794-145-56 |
| Digoxin Tablets, USP | 0.25mg | 100 | 62794-146-01 |
| | | 1,000 | 62794-146-10 |
| | | 5,000 | 62794-146-56 |

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EXHIBIT B**TRANSFER PRICE**

| <u>Product Name</u> | <u>Strength</u> | <u>Bottle Size</u> | <u>NDC No.</u> | <u>Price</u> |
|----------------------------|------------------------|---------------------------|-----------------------|---------------------|
| Digoxin Tablets, USP | 0.125mg | 100 | 62794-145-01 | \$ 1.24 |
| | | 1,000 | 62794-145-10 | \$10.51 |
| | | 5,000 | 62794-145-56 | \$51.23 |
| Digoxin Tablets, USP | 0.25mg | 100 | 62794-146-01 | \$1.40 |
| | | 1,000 | 62794-146-10 | \$12.14 |
| | | 5,000 | 62794-146-56 | \$59.77 |

(000249 - 00008 / 00038356.DOC;1)

EXHIBIT C
RESIDUAL DUE CALCULATION

| | Dollars | Units |
|---|---------|-------|
| Gross Sales | X | X |
| Less: | | |
| Customer Performance Rebates | X | |
| Chargebacks | X | |
| Other Rebates | X | |
| Government Rebates | X | |
| Sales and Quantity Discounts | X | |
| Other Discounts | X | |
| Physical Returns: | | |
| From customer and returned into inventory | X | X |
| From customer and destroyed | X | X |
| Net Sales | X | X |
| Net Sales | X | |
| Less Transfer Price | X | |
| Gross Margin | X | |
| Times 39% 35% | X | |
| Residual Due | X | |

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EXHIBIT D

(000249 - 00008 / 00038356.DOC;1)

Sent by: AMIDE PHARMACEUTICAL, INC.

973 890 7980;

06/07/99 12:55PM; JetFax #61; Page 2/14

**KAISER-PERMANENTE MEDICAL CARE PROGRAM
REQUEST FOR QUOTATION - NOT AN ORDER -
FROM: 0555 AMIDE PHARMACEUTICALS INC.**

| QUANTITY | DESCRIPTION UNIT | STOCK # | UNIT PRICE | MFR TRADE NAME | CASE LOT |
|----------|---------------------------------|---------|---------------|------------------------|-------------|
| 2029 | DIGOXIN TABLETS USP 0.25 MG (6) | | | | |
| 70,000 | 100/BT | 42228 | \$ 3.30 | Digoxin Tab 0.25 mg | 24 X C |
| 30 | 5000/BT | 42240 | \$125.50 | | 12 X5M |
| 300 | 100/BX UD | 42261 | \$ 8.95 | | --- |

* * * Also Available Digoxin Tablets 0.125 mg

Prices: 100's \$ 3.30
1000's \$ 26.25
5000's \$ 125.50

1/12/96

Additional Quotation

Digoxin Tablets 0.5 mg

Prices: 100's \$ 5.25

06/07/99 MON 12:32 [TX/RX NO 7862]

Sent by: AMIDE PHARMACEUTICAL, INC.

973 890 7980;

06/07/99 12:55PM; JetFax #61; Page 3/14

Kaiser Permanente Medical Care Program
 Pharmaceutical Operations
 300 Pullman Street
 Livermore, California 94550-9756
 (510) 294-7190
 FAX: (510) 294-7188



DATE: February 16, 1996

REF: Agreement # 0555-99-M-5

Mr. Chandu Patel
 President
 Amide Pharmaceuticals
 101 E. Main St.
 Little Falls, NJ 07414

ADDITION TO AGREEMENT

This is to confirm changes in Agreement as established with Mr. Bharat Patel on January 12, 1996. Except as specifically modified by this Amendment, all terms and conditions of the existing Agreement shall remain in full force and effect.

EFFECTIVE DATE;
 March 1, 1996

EXPIRATION DATE;
 December 31, 1998

| <u>Digoxin Tablets USP:</u> | | | | Case Size; |
|-----------------------------|-------|--------|---------|------------|
| 2027 0.125 mg | 100 | \$3.30 | #145-02 | 24 |
| | 1,000 | 26.25 | -05 | 24 |
| | 5,000 | 125.50 | -06 | 12 |
| 2029 0.25 mg | 100 | 3.30 | #146-02 | 24 |
| | 1,000 | 26.25 | -05 | 24 |
| | 5,000 | 125.50 | -06 | 12 |
| | 100UD | 8.95 | -00 | 1 |
| 0.5 mg | 100 | 5.25 | #147-02 | 24 |

Subject to approval and product acceptability per Program Region.

C. D. Frith
 Purchasing Agent

Page 1 of 1

06306-05 (1-95)

06/07/99 MON 12:32 [TX/RX NO 76621]

Sent by: AMIDE PHARMACEUTICAL, INC.

973 890 7980;

06/07/99 12:55PM; JafFax #61; Page 4/14

Kaiser Permanente Medical Care Program
Pharmaceutical Operations
300 Pullman Street
Livermore, California 94550-9756

(510) 294-7190
FAX: (510) 294-7188



ACREEMENT:

We request that contract prices be made available to all Program Regions via the wholesale Distributor listed below. The Program shall rely on the availability of contract pricing on the effective date of Agreement unless notice to the contrary is received by the Program Purchasing Office in Northern California not later than ten days from Notice of Award. Invoices in excess of contract prices (inclusive of customary service charges) shall otherwise not be honored.

Northern California
(Primary)
McKesson Drug Co.
P. O. Box 15858
Sacramento, CA 95852
(800) 952-5403

Northern California
(Secondary)
Bergen Brunswig Co.
P. O. Box 13100
Sacramento, CA 95813
(800) 635-4907

Southern California
(Primary)
Bergen Brunswig Co.
4000 Metropolitan Dr.
Orange, CA 92668
(714) 385-4402

Southern California
(Secondary)
Barnes Wholesale Drug
740 Claglow
Inglewood, CA 90301
(310) 641-1885

Colorado Region
(Primary)
McKesson Drug Co.
14500 E. 39th Ave
Aurora, CO 80011
(303) 371-0770

Colorado Region
(Secondary)
Bergen Brunswig Co.
501 W. 44th Ave
Denver, CO 80216
(303) 433-6644

Georgia Region
(Primary)
McKesson Drug Co.
2975 Evergreen Dr.
Duluth, GA 30136
(770) 813-8145

Georgia Region
(Secondary)
Bergen Brunswig Co.
1085 N. Satellite Blvd.
Suwanee, GA 30174
(770) 623-3193

Hawaii Region
(Primary)
McKesson Drug
80 Sand Island Access Rd
Honolulu, HI 96819
(808) 847-3911

Hawaii Region
(Secondary)
Bergen Brunswig Co.
99-810 Iwaena St.
Aiea, HI 96701
(808) 487-3691

Kansas Region
(Primary)
Bergen Brunswig Co.
1501 Southern Rd
Kansas City, MO 64120
(816) 241-8000

Kansas Region
(Secondary)
McKesson Drug Co.
1 Commerce Dr.
St. Peters, MO 63376
(314) 970-1991

Mid-Atlantic States
(Primary)
Bergen Brunswig Co
9900 Jeb Stuart Pkwy.
Glen Ellen, VA 23060
(800) 446-8209

North Carolina Region
(Primary)
Kendall Drug Co
1305 Frederick St
Shelby, NC 28150
(704) 482-2481

North Carolina Raleigh Area
(Secondary)
Bergen Brunswig Co
8605 Ebenezer Church Rd.
Raleigh, NC 27613
(919) 782-8400

North Carolina /Charlotte
(Secondary)
Bergen Brunswig Co
1085 Satellite Blvd.
Suwanee, GA 30174
(770) 623-3193

Northeast Region
(Primary)
McKesson Drug Co
280 Dividend Rd
Rocky Hill, CT 06067
(800) 243-8402

Northwest Region
(Primary)
Bergen Brunswig Co
6505 SW 110 Court
Beverton, OR 97008
(503) 641-6414

Northwest Region
(Secondary)
McKesson Drug Co
9700 So West Commerce Cir
Wilsonville, OR 97070
(800) 452-3140

Ohio Region
(Primary)
Bailey Drug Co
1000 Linden Ave
Zanesville, OH 43701
(614) 453-0591

Ohio Region
(Secondary)
Amerisource Corp
3145 Nebraska Ave
Tolodo, OH 43607
(800) 688-2526

Texas Region
(Primary)
McKesson Drug Co
809 110th Street
Arlington, TX 76011
(817) 640-6333

Texas Region
(Secondary)
Bergen Brunswig Co
1841 Monetary Lane
Carrollton, TX 75006
(214) 245-9236

REV 10/95

03906-00 (1-95)

06/07/99 MON 12:32 (TX/RX NO 76621)

Sent by: AMIDE PHARMACEUTICAL, INC.

973 890 7980;

06/07/99 12:56PM; JettFax #61; Page 5/14

**KAISER PERMANENTE MEDICAL CARE PROGRAM
REGIONAL PHARMACY PURCHASING OFFICES**

NORTHERN CALIFORNIA

CLIVE D. FRITH
PURCHASING AGENT
KAISER FOUNDATION HOSPITALS
300 PULLMAN STREET
LIVERMORE, CA 94590
(510) 294-7190 FAX (510) 294-7188

COLORADO

JAIRO RAMIREZ
MANAGER DRUG PURCHASING
KAISER FOUNDATION HEALTH PLAN
16601 EAST CENTRETECH PKWY
AURORA, CO 80011
(303) 739-3557 FAX (303) 739-3574

HAWAII

RONALD TANIGUCHI
ASSISTANT PHARMACY DIRECTOR
KAISER FOUNDATION HOSPITALS
99-807 IWAENA STREET
AIEA, HI 96701
(808) 488-2637 FAX (808) 487-7314

MID-ATLANTIC STATES

DARWIN LINDGREN
RESTON PHARMACY
KAISER FOUNDATION HEALTH PLAN
11445 SUNSET HILLS RD
RESTON, VA 22090
(703) 709-1637 FAX (703) 709-1744

NORTHEAST

DAN ANSELMO
REGIONAL PHARMACY DIRECTOR
KAISER PERMANENTE
76 BATTERSON PARK RD
FARMINGTON, CT 06034
(203) 678-6176 FAX (203) 678-6160

OHIO

DEBBIE ROYAK
MANAGER PHARMACY PURCHASING
KAISER FOUNDATION HEALTH PLAN
5420 LANCASTER DRIVE
BROOKLYN HEIGHTS, OH 44131
(216) 749-8408 FAX (216) 749-8426

SOUTHERN CALIFORNIA

ROBERT M. TOOMAJIAN
MANAGER OF DRUG PURCHASING
KAISER FOUNDATION HOSPITALS
9521 DALEN STREET
DOWNEY, CA 90242
(310) 803-2959 FAX (310) 803-2944

GEORGIA

LESLIE M. LITTON
DIRECTOR OF PHARMACY
KAISER PERMANENTE
3495 PIEDMONT RD, NE
ATLANTA, GA 30305
(404) 364-4824 FAX (404) 364-4798

KANSAS CITY

DIANA MORASCH
DIRECTOR OF PHARMACY
KAISER FOUNDATION HEALTH PLAN
10561 BARKLEY, STE. #200
OVERLAND PARK, KS 66212
(913) 967-4675 FAX (913) 642-0209

NORTH CAROLINA

TIM KUREK
DIRECTOR PHARMACY SERVICES
KAISER FOUNDATION HEALTH PLAN
951 AVIATION PARKWAY
MORRISVILLE, NC 27560
(919) 460-9697 FAX (919) 460-9761

NORTHWEST

STEPHEN J. MILLER
PHARMACY SUPPLY CENTER
KAISER PERMANENTE
10200 S.E. SUNNYSIDE RD
CLACKAMAS, OR 97015
(503) 652-5718 FAX (503) 652-5769

TEXAS

LAURA MEHL
ASSISTANT DIRECTOR OF PHARMACY
KAISER FOUNDATION HEALTH PLAN
12720 HILLCREST RD #600
DALLAS, TX 75230
(214) 458-5184 FAX (214) 458-5173

9/94

06/07/99 MON 12:32 [TX/RX NO 7682]

Sent by: AMIDE PHARMACEUTICAL, INC.

973 890 7980;

06/07/99 12:56PM; JetFax #61; Page 6/14.

INSTRUCTIONS FOR SUBMITTING QUOTATIONS

To facilitate the completion of the documents necessary for submission of a Request for Quotation to the Kaiser Permanente Medical Care Program, please follow these instructions.

Terms and Conditions: Our Requests for Quotation identify terms and conditions issues that need to be addressed. We will consider alternatives but must know the details of any exceptions desired. Awards and Acceptances will be issued on Program documents to reflect mutually agreeable terms and conditions.

Single & Multi-Source Products: Requests for Quotation are designated accordingly.

"Single Source" products may be considered for potential therapeutic interchangeability. Only those offered on a long term basis will be considered. Decisions on acceptability and interchangeability are reserved to the Program.

"Multi-Source" products; The Program's intention is to standardize on particular manufacturers' products and commit to purchase substantially all its requirements reflected by the usage estimates contained in Requests for Quotations or otherwise confirmed during the period of Agreements. Offers of economically advantageous alternatives and quantities are encouraged, including quantity withdrawals, bulk packaging, alternative dosage forms, and different periods of Agreement. Mere price quotations without commitment to supply are of little value. Awards as primary sources of supply will be limited to proposals with supply commitments.

XPMCP/RFQ INSTR (5/95)

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06/07/99 MON 12:32 [TX/RX NO 7662]

Sent by: AMIDE PHARMACEUTICAL, INC.

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06/07/99 12:56PM; JetFax #61; Page 7/14

Packaging:

"Unit of Use" packaging where particularly desired by the Program is designated with a "(6)" at descriptions for Multi-Source Items. Packaging specifications that differ from the Program's will be considered.

Injectables: Injectables must be identified as ampules of vials, single or multi-dose, lyophilized, or in solution, with diluents and preservatives identified. Multi-Source items where this information is required are designated with a "(1)" at the end of descriptions.

Unit Dose: Controlled Substances: Reverse numbered packaging is preferred if available. Quotations should be identified as "RNP" where applicable.

OTC Labelling: If over the counter labelling is available please specify accordingly.

FORMAT FOR REPLIES:

ONLY QUOTATIONS SUBMITTED ON THE FORMS WE PROVIDE WILL BE CONSIDERED. Additional material may be included if necessary to supplement responses.

Prices: Price Quotations must be expressed in terms of the units specified on the enclosed forms (not multiples) and entered on the Program documents supplied. Only two places of decimals will be considered operative. Shipping requirements must be signified as quantities of these units in the "Case Lot" column (Example: 12, 24, 144 etc). "Case" quantities will not be considered mandatory for ordering purposes, unless so specified.

Units: Abbreviations used are as follows;

| | | | | | |
|-----|--------|-----|------------|--------------|-----------------|
| /BT | Bottle | /ML | Milliliter | /BX | Box (unit dose) |
| /CS | Case | /DS | Dose | 1/Gm, or 1/G | One Gram |

Product Codes and Stock Numbers: NDC numbers are needed for all items quoted. Price lists that include this information for each stock keeping unit can be supplied as addenda to satisfy this requirement.

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973 890 7980;

06/07/99 12:57PM; JetFax #61; Page 8/14

Manufacturer Identification: WHERE DIFFERENT FROM THE SUPPLIER SUBMITTING QUOTATIONS, the identity of the manufacturer of the finished dosage form must be shown in the designated column of the Request for Quotation. If Sellers have trade names that apply to Multi-Source quotations offered, include them for each product offered.

Returns: Suppliers' returns policies and procedures for outdated and other material must be provided as part of quotations and summarized in the Request for Quotation forms if they differ from those we propose.

The preferred arrangement is to return all material that is out of date, or for other reasons unusable, without formalities or prior authorization (Exceptions: recalls, defective products, ordering or shipping errors). In lieu of credit, check or product exchange, an annual rebate as a mutually agreed percentage of all purchases is proposed to eliminate or reduce the costs of routine authorization, handling, shipping, review and administration for both the Program and its suppliers.

Forms and Documents:

Quotations and offers must be entered on the Program's original documents, and signed and dated where indicated on page six of the Request for Quotation form. Addenda may be included if necessary to complete replies.

To consider proposals, the following documents must be returned to us:

- (a) Our Original Request for Quotation Forms
- (b) The List of products requested for quotation (all pages whether quoted or not)
- (c) Vendor Information Form
- (d) Supplier's Published Price List to Wholesale Distributors
- (e) Attachments and exhibits.

(If FAX is used, hard copies of originals must follow as confirmation)

Sent by: AMIDE PHARMACEUTICAL, INC.

973 890 7980;

06/07/99 12:57PM; JetFax #61; Page 9/14

~~Other documents such as Standard Purchase Order Form, Instructions for Bid Submission, List of Regional Purchasing Offices, and Packaging Specifications are for the information of suppliers and should not be included in your submissions.~~

Request for Information (Page 7): Detailed information is necessary for processing orders, shipments, inventories, returns, establishment of lead times, and the indemnification process regarding supply commitments. We will rely on lead times set forth in your response and will request indemnification for excess acquisition costs if we are forced to purchase replacement material elsewhere because of failures to supply except under circumstances beyond your control.

Dates Due for Return: Responses to Requests for Quotation are due on the date stated on Page One of the Request for Quotation Form (If more time is needed, please call so that alternate arrangements can be made).

Acknowledgments and Awards: Acceptances and awards will be by written Notice originated by the Program.

**DIRECT REPLIES AND INQUIRIES TO:
KAISER PERMANENTE MEDICAL CARE PROGRAM
C/O PHARMACEUTICAL OPERATIONS
300 PULLMAN ST.**

LIVERMORE, CA 94550

TEL: (510) 294 7190

FAX: (510) 294 7188

KPMCP/RFQ INSTR (5/95)

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06/07/99 MON 12:32 [TX/RX NO 7662]

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PLAINTIFFS' EXHIBITS 013182

agreement clause as certain sentence. A clause which conflicts by accepting this sentence

11. **CORRELATION IN CERTAIN CASES.** There is in the present paper, it is pointed out, a need for a research which may be called the "intermediate" or "intermediate" research, which is a research which is not yet a research in the sense of the present paper, but which is a research in the sense of the present paper, and which is a research in the sense of the present paper.

8. **SOURCING LAW.** The laws of the State of California still govern the validity, enforceability and enforcement of purchaser's rights. Purchaser's remedy provided for herein and by law shall be cumulative.

Sent by: AMIDE PHARMACEUTICAL, INC.

973 890 7980;

08/07/99 12:58PM; JettFax #61; Page 12/14



KAISER PERMANENTE

UNIT OF USE PRODUCTS PACKAGING SPECIFICATIONS

Packaging specifications described below address the current needs of the Kaiser Permanente Medical Care Program. Exceptions to these specifications may be considered. Acceptance of any packaging variances must be obtained in writing. All suppliers are encouraged to contact the Pharmacy Materials Manager to discuss packaging requirements.

A. CONTAINER

1. Container closure system must have approved child-resistant closures and meet appropriate USP container specifications for the type of product stored in that container.
2. The container must have the minimum dimensions (height, from shoulder to base 2 3/8 inches, circumference 4 inches).
3. Container should be the smallest size possible, with the above minimum dimensions.
4. Tablets or capsules should be packed to prevent powdering or breakage.

B. PACKAGE INSERTS

1. Package insert should be supplied loose inside shelf or shipping package and not be inside or attached to the unit-of-use container.

C. SHELF OR SHIPPING PACKAGES

1. Unit-of-use containers should be shrink wrapped in units of twelve. Shrink-wrapped packs can be consolidated into larger shipping containers. Shipping containers should be labeled. Label should indicate number of units, unit name, and size.

D. LABELS (Example on reverse)

1. Format

- a. 2 part
- b. Size 1 1/2" high by 3 3/8" wide.
- c. Drug name, strength, minimum size 14 points (bold face capitals).
- d. Quantity and dosage form 10 points (bold face capitals).

2. Right Hand Portion of Label

- a. Printing left to right.
- b. Copy meets all regulatory requirements of FDA, DEA, etc.
- c. Size and dosage form at top of label, above drug name.
- d. Drug name and strength, upper half of label.
- e. Different strengths of the same dosage form shall be differentiated by color coding.

3. Left Hand Portion of Label

- a. Non removable
- b. Printing should be perpendicular to the base of the container.
- c. Quantity, dosage form, name, strength, top of label.
- d. Lot number, lower portion of label.
- e. Expiration date, lower portion of label expressed as: "Discard after".
- f. Storage requirements
- g. Information or appropriate cautions: e.g., refrigerate, dizzy, drowsy caution, etc.
- h. Manufacturer's name.

37 (2-89)

08/07/99 MON 12:32 [TX/RX NO 7662]

Sent by: AMIDE PHARMACEUTICAL, INC.

973 890 7980;

06/07/99 12:58PM; JetFax #61; Page 13/14

Kaiser Permanente Medical Care Program
 Pharmaceutical Operations
 300 Pullman Street
 Livermore, California 94550-9756
 (510) 294-7190
 FAX: (510) 294-7188



DATE: May 26, 1998
 REF: Agreement # 0555-99-M-5
 * Revision

Amide Pharmaceuticals
 Mr. Chandu Patel
 President
 101 E. Main St.
 Little Falls, NJ 07414

EXTENSION OF AGREEMENT

This is to confirm changes in Agreement as established with Ms. Sharon English on May 26, 1998. Except as specifically modified by this Amendment, all terms and conditions of the existing Agreement shall remain in full force and effect.

EFFECTIVE DATE:
 January 1, 1999

EXPIRATION DATE:
 December 31, 2000

| <u>Digoxin Tablets USP</u> | | | <u>#52152-</u> | <u>Case Size:</u> |
|----------------------------|----------|-------|----------------|-------------------|
| 2027 | 0.125 mg | 100 | 0145-02 | 24 |
| | | 1,000 | -05 | 24 |
| | | 5,000 | -06 | 12 |
| | | | | |
| 2029 | 0.25 mg | 100 | 0146-02 | 24 |
| | | 1,000 | -05 | 24 |
| | | 5,000 | -06 | 12 |
| | | 100UD | -00 | 1 |
| | | | | |
| 2030 | 0.5 mg | 100 | 0147-02 | 24 |

Sincerely,

Richard M. Lieblich
 Purchasing Agent

cc: Program Regions
 * Wholesalers

06/06/99 (1:05)

06/07/99 MON 12:32 [TX/RX NO 7662]

Sent by: AMIDE PHARMACEUTICAL, INC.

973 890 7980;

08/07/99 12:59PM; JetFax #61; Page 14/14

KAISER PERMANENTE MEDICAL CARE PROGRAM PURCHASE AGREEMENT: EDITION
FOR WHOLESALE DISTRIBUTORS. "CONFIDENTIAL" NOT AUTHORIZED FOR ANY
PURPOSE EXCEPT IMPLEMENTATION OF DEPOT CHARGE-BACKS ON PROGRAM
PURCHASE ORDERS.



KAISER PERMANENTE

Kaiser Permanente Medical Care Program
Pharmaceutical Operations
300 Puffman Street
Livermore, California 94550-9756

(510) 294-7190

Fax: (510) 294-7188

ManufacturerContract #

| <u>Contract #</u> | <u>Manufacturer</u> | <u>Start Date</u> | <u>End Date</u> | <u>NDC#</u> | <u>Description</u> | <u>Unit</u> | <u>Price</u> |
|-------------------|---------------------------|-------------------|-----------------|---------------|----------------------|-------------|--------------|
| 0555-99-M-5 | AMIDE PHARMACEUTICAL INC. | 1/1/99 | 12/31/00 | 52152-0145-02 | DIGOXIN TABS 0.125MG | 100 | 3.30 |
| 0555-99-M-5 | AMIDE PHARMACEUTICAL INC. | 1/1/99 | 12/31/00 | 52152-0145-05 | DIGOXIN TABS 0.125MG | 1000 | 26.25 |
| 0555-99-M-5 | AMIDE PHARMACEUTICAL INC. | 1/1/99 | 12/31/00 | 52152-0145-06 | DIGOXIN TABS 0.125MG | 5000 | 125.50 |
| 0555-99-M-5 | AMIDE PHARMACEUTICAL INC. | 1/1/99 | 12/31/00 | 52152-0148-02 | DIGOXIN TABS 0.25MG | 100 | 3.30 |
| 0555-99-M-5 | AMIDE PHARMACEUTICAL INC. | 1/1/99 | 12/31/00 | 52152-0148-05 | DIGOXIN TABS 0.25MG | 1000 | 26.25 |
| 0555-99-M-5 | AMIDE PHARMACEUTICAL INC. | 1/1/99 | 12/31/00 | 52152-0148-06 | DIGOXIN TABS 0.25MG | 5000 | 125.50 |
| 0555-99-M-5 | AMIDE PHARMACEUTICAL INC. | 1/1/99 | 12/31/00 | 52152-0148-00 | DIGOXIN TABS 0.25MG | 100 U/D | 8.95 |
| 0555-99-M-5 | AMIDE PHARMACEUTICAL INC. | 1/1/99 | 12/31/00 | 52152-0147-02 | DIGOXIN TABS 0.5MG | 100 | 5.25 |

08/07/99 MON 12:32 [TX/RX NO 7662]

PLAINTIFFS' EXHIBITS 013186

09517 (8-97)

EXHIBIT E

{000249 - 00008 / 00038356.DOC;1}

TRADEMARK LICENSE AGREEMENT

THIS TRADEMARK LICENSE AGREEMENT ("Agreement") is entered into as of August 5, 1999 ("Effective Date"), between:

Mylan Laboratories, Inc.
A Pennsylvania Corporation
with an office located at
781 Chestnut Ridge Road
Morgantown, West Virginia 26505
and

Bertek Pharmaceuticals Inc.
a Texas Corporation,
(Hereinafter collectively referred to as
"BERTEK") with offices located at
3711 Collins Ferry Road
Morgantown, West Virginia 26505

and

Amide Pharmaceuticals, Inc.
a New Jersey Corporation,
(hereinafter referred to as
"AMIDE") with offices located at
101 East Main Street
Little Falls, New Jersey 07424

WHEREAS, BERTEK and AMIDE have entered into a Supply and Distribution Agreement dated August 5, 1999, hereinafter referred to as "Supply and Distribution Agreement"; and

WHEREAS, the Supply and Distribution Agreement provides for BERTEK to license the Trademark (as defined in the Supply and Distribution Agreement) to AMIDE, only upon the occurrence of certain events as identified in Sections 8.1(c) and 8.4 of the Supply and Distribution Agreement; and

WHEREAS, BERTEK is willing, under the terms and conditions as hereinafter set forth, to permit AMIDE to use BERTEK'S Trademark in connection with the distribution, marketing and sale of the Product (as defined in the Supply and Distribution Agreement); and

WHEREAS, AMIDE desires to acquire the right from BERTEK to use the Trademark, in connection with the distribution, marketing and sale of the Product.

WITNESSETH THEREFORE that in consideration of the premises set forth and covenants exchanged herein and for other good and valuable consideration, the sufficiency and receipt of all of which are hereby acknowledged, BERTEK and AMIDE intending to be legally bound agree as follows:

ARTICLE I
GRANT

Subject to the terms and conditions of this Agreement, BERTEK hereby grants to AMIDE, and AMIDE hereby accepts, an exclusive right and license, with the right to grant sublicenses on terms subject to and consistent with this Agreement, to use the Trademark during the term of this Agreement in connection with the Commercialization (as defined in the Supply and Distribution Agreement) of the Product throughout the Territory. During the term of this Agreement BERTEK shall not use the Trademark or grant any other person any rights to use the Trademark in the Territory. During the term of this Agreement, AMIDE shall not use the Trademark for any purpose other than in connection with the Commercialization of the Product. AMIDE shall not use the Trademark or authorize any of its Affiliates or sublicensees to use the Trademark outside the Territory.

For further clarification, the parties specifically acknowledge it is their intention that the license described herein, shall be deemed effective only at such time, if ever, that the events set forth in Sections 8.1(c) and 8.4 of the Supply and Distribution Agreement have occurred.

ARTICLE II
GENERAL TERMS AND CONDITIONS

2.1 Trademark Rights

(1) Ownership. AMIDE acknowledges that as between BERTEK and AMIDE the Trademark belongs to BERTEK. During the term of this Agreement and thereafter, AMIDE shall not challenge BERTEK's ownership in or rights to the Trademark, or attempt to register the Trademark in its own name.

(2) Maintenance. It shall be BERTEK's responsibility to undertake during the term of this Agreement the maintenance of the Trademark in the Territory. In the event there is an occurrence of the events set forth in Sections 8.1(c) and 8.4 of the Supply and Distribution Agreement, BERTEK will continue to assume responsibility for maintenance of the Trademark, but AMIDE shall be responsible for all expenses related thereto. In connection with BERTEK's maintenance of the Trademark, AMIDE shall cooperate with BERTEK by executing any necessary documents, supplying BERTEK with specimens and performing other reasonable acts, as requested by BERTEK in writing from time-to-time.

(3) Infringement or Other Actions

(i) If BERTEK or AMIDE shall become aware of any actual or threatened infringement of the Trademark in the Territory or any actual or threatened unfair competition, disparagement or other tortious act by any third-party in relation to the Trademark, then the party having such knowledge shall give notice to the other within ten (10) days of becoming aware of such actual or threatened infringement, unfair competition, disparagement or other tortious act.

(ii) AMIDE shall take such action as it deems reasonably necessary to protect and enforce the Trademark in the Territory, including but not limited to bringing an action, suit or other appropriate proceeding to prevent or eliminate the infringement of such Trademark, or the unfair competition, disparagement or other tortious act by any third party in relation to the Trademark in the Territory. BERTEK agrees to cooperate with AMIDE in any reasonable manner in any such action, suit or proceeding, at AMIDE's expense, including joining as a party to such action, suit or proceeding, if necessary to maintain standing. If AMIDE elects not to take such action and so notifies BERTEK, or if it fails to take such action within sixty (60) days of becoming aware of actual infringement, unfair competition, disparagement or some other tortious act, BERTEK shall have the right (but not the obligation) to take such action at its expense. In such event, AMIDE shall cooperate with BERTEK in any reasonable manner in any such action, suit or proceeding, at BERTEK's expense. Any money recovered by way of damages or otherwise in respect of any such action shall be kept solely by the party that bore the costs of such action. BERTEK shall have no obligation hereunder or otherwise to protect and enforce the Trademark against any actual threatened infringement, unfair competition, disparagement or other tortious act.

2.2 Third Party Claims. If BERTEK or AMIDE shall become aware of any action, suit or proceeding or threat of action, suit or proceeding, by a third party alleging that the use of the Trademark in the Territory infringes a trademark or violates any other proprietary right of any third party, the party so aware shall promptly notify the other party of the same and fully disclose the basis therefore.

2.3 Quality Control

(1) AMIDE and its Affiliates shall not use the Trademark in any manner which will tarnish or disparage the Trademark or otherwise have a material adverse effect upon the Trademark or the goodwill associated therewith.

(2) The Trademark shall be used in substantially the same form as it was heretofore used by BERTEK in connection with the Product. In the event AMIDE or any of its Affiliates wishes to use the Trademark in a substantially different form, AMIDE shall submit such different form to BERTEK for approval, which shall not be unreasonably withheld or delayed.

(3) The nature and quality (including all packaging and other materials associated therewith) of all Product manufactured by AMIDE or for AMIDE by any third-party, and the advertising of all Product sold by AMIDE or any of its Affiliates, sublicensees or distributors bearing any Trademark shall be of a quality at least as high as the Product heretofore sold under the Trademark by BERTEK and the advertising heretofore associated therewith, as the case may be. AMIDE shall, and shall cause its Affiliates to, comply with applicable federal, state and local laws, rules and regulations in distributing, marketing, promoting, advertising, selling, storing and packaging the Product including without limitation all FDA rules and regulations and all applicable portions of the ANDA approval for the Product.

(4) BERTEK shall have the following rights to exercise quality control over AMIDE's use of the Trademark to assure AMIDE's adherence to the standards set forth in Section 2.3(a), (b) and (c):

(i) AMIDE shall upon request by BERTEK, from time to time, submit to BERTEK a reasonable number of samples of any Product and any packaging, advertising and other materials which bear or are used with the Trademark, provided however, that nothing in this Section 2.3 shall be deemed to give BERTEK the right to preapprove, prior to the initial dissemination thereof, the advertising, packaging, and other materials used by AMIDE in connection with the Product; and

(ii) With respect to any Product, BERTEK shall have the right, during regular business hours, after reasonable advance written notice to AMIDE, to undertake up to two (2) inspections per annum of any facilities used to manufacture or store such Product.

ARTICLE III

TERM AND RIGHTS ON EXPIRATION OR TERMINATION

3.1 The term of this Agreement shall commence on the Effective Date and shall continue for as long as AMIDE or one of its Affiliates or sublicensees is continuing to market the Product in the Territory.

3.2 Upon the termination or expiration of this Agreement: (i) all rights granted hereunder to AMIDE with respect to the Trademark shall revert to BERTEK; and (ii) AMIDE shall cease using the Trademark.

ARTICLE IV

DEFAULT; REMEDIES

4.1 If BERTEK or AMIDE commits a material breach of this Agreement or materially defaults in the performance or observance of any provision of this Agreement and fails to remedy such breach or default within sixty (60) days after receipt of notice thereof, such occurrence shall

constitute an "Event of Default" under this Agreement.

4.2 Immediately upon the occurrence of any Event of Default by BERTEK pursuant to Section 4.1 hereof, AMIDE shall have the right to terminate this Agreement, exercisable by delivering written notice thereof to BERTEK, and/or to pursue any and all remedies available to it at law or in equity.

4.3 Immediately upon the occurrence of any Event of Default by AMIDE pursuant to Section 4.1 hereof, BERTEK shall have the right to terminate this Agreement, exercisable by delivering written notice thereof to AMIDE, and/or to pursue any and all remedies available at law or in equity.

4.4 The parties expressly acknowledge that the remedy provisions contained in this Article IV are reasonable, considering the intended nature and scope of this Agreement.

4.5 If BERTEK or AMIDE terminates this Agreement in accordance with the terms herein, the terminating party shall owe no statutory termination penalty or indemnity or other similar payment that might otherwise be due under local law to the terminated party on account of such termination.

4.6 The obligations of BERTEK and AMIDE under this Agreement shall be subject to any delays or non-performance caused by: acts of God, earthquakes, fires, floods, explosion, sabotage, riot, accidents; regulatory, governmental, or military action or inaction; strikes, lockouts or labor trouble; perils of the sea; or failure or delay in performance by third parties, including suppliers and service providers; or any other cause beyond the reasonable control of either party. The party which is not performing its obligations under this Agreement as a result of any such event of force majeure shall use Commercially Reasonable Efforts (as defined in the Supply and Distribution Agreement) to resume compliance with this Agreement as soon as possible.

ARTICLE V TRADEMARK ROYALTY PAYMENTS

5.1 AMIDE shall pay to BERTEK a Trademark royalty in the amount of ten percent (10%) of AMIDE's Net Sales on the Products. Net Sales shall have the same definition as that in Section 1.17 of the Supply and Distribution Agreement, except that "BERTEK" in said definition shall be changed to "AMIDE".

5.2 The calculation of AMIDE's Net Sales and BERTEK's ten percent (10%) of the Net Sales shall be paid to BERTEK within forty-five (45) days after the end of the Calendar Quarter (as defined in the Supply and Distribution Agreement).

5.3 All payments required to be made to BERTEK under this Agreement shall be made in United States dollars and may be made by either wire or paper transfer on the due date to the following address:

Bertek Pharmaceuticals Inc.
781 Chestnut Ridge Road
Morgantown, WV 26505
Attn: William W. Richardson
President, CEO

or to any other address that BERTEK may advise in writing.

ARTICLE VI
MISCELLANEOUS

6.1 In making and performing this Agreement, the parties are acting and shall act as independent contractors. Nothing in this Agreement shall be deemed to create an agency, joint venture or partnership relationship between BERTEK and AMIDE. No party shall have the authority to obligate the other party in any respect, and no party shall hold itself out as having any such authority. All personnel of BERTEK shall be solely employees of such party and shall not represent themselves as employees of AMIDE. All personnel of AMIDE shall be solely employees of AMIDE and shall not represent themselves as employees of BERTEK.

6.2 AMIDE may not assign or otherwise transfer any of its rights or obligations hereunder without prior written consent of BERTEK, which shall not be unreasonably withheld or delayed; provided, however, that no such consent shall be required in the case of an assignment by AMIDE to one of its Affiliates. No such assignment shall relieve AMIDE of any of its obligations or liabilities under this Agreement. Nothing herein shall be deemed or construed to prohibit AMIDE from sublicensing the Trademark to its Affiliates as permitted herein.

6.3 This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective successors and permitted assigns. Nothing contained herein shall give to any other person any benefit or any legal or equitable right, remedy or claim.

6.4 This agreement may not be modified, amended or supplemented by an instrument in writing executed by BERTEK and AMIDE.

6.5 No term or provision hereof will be considered waived by either party, and no breach excused by either party, unless such waiver or consent is in writing signed on behalf of the party against whom the waiver is asserted. No consent by either party to, or waiver of, a breach by either party, whether express or implied, will constitute a consent to, waiver of, or excuse of any other, different, or subsequent breach by either party.

6.6 Any notices or reports required or permitted under this Agreement shall be deemed to have been given for all purposes if mailed by first class certified or registered mail or transmitted electronically by facsimile with mailed confirmation copy to the following address

of either Party:

For BERTEK: BERTEK Pharmaceuticals Inc.
781 Chestnut Ridge Road
Morgantown, WV 26505
Attn: William W. Richardson
President, CEO

For AMIDE: Amide Pharmaceutical, Inc.
101 East Main Street
Little Falls, New Jersey 07424
Attn: Chandu Patel, President

or to such other addresses as shall have been subsequently furnished by written notice to the other Party.

6.7 This Agreement shall become binding when any one or more counterparts hereof, individually or taken together, shall bear the signatures of each of the parties hereto. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original as against the party whose signature appears thereon, but all of which taken together shall constitute but one and the same instruments.

6.8 The article and section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

6.9 Any of the provisions of this Agreement which are determined to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability in such jurisdiction, without rendering invalid or unenforceable the remaining provisions hereof or affecting the validity or enforceability of any of the provisions of this Agreement in any other jurisdiction.

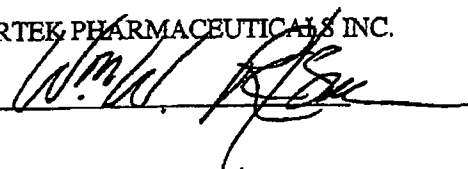
6.10 This Agreement and the other agreements contemplated hereby or thereby or executed concurrently herewith embody the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersede all prior agreements, commitments, arrangements, negotiations or understandings, whether oral or written, between the parties hereto and their respective Affiliates with respect thereto. There are no agreements, covenants or undertakings with respect to the subject matter of this Agreement and the other agreements contemplated hereby to thereby other than those expressly set forth or referred to herein or therein and no representations or warranties of any other kind or nature whatsoever, express or implied, are made or shall be deemed to be made herein by the parties hereto except those expressly made in this Agreement and the other agreements contemplated hereby or thereby.

6.11 Each party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be reasonably necessary or appropriate in order to carry out the purposes and intent of this Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

BERTEK PHARMACEUTICALS INC.

By



Title President & Chief Executive Officer

Date August 5, 1999

AMIDE PHARMACEUTICAL, INC.

By

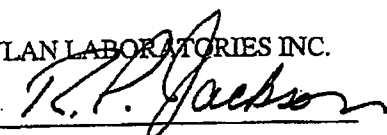


Title PRESIDENT

Date 8/5/99

MYLAN LABORATORIES INC.

By



Title Senior Vice President

Date August 5, 1999

May 25, 2005 2:44PM MYLAN LEGAL

NO. 232 P. 2

Amide
PHARMACEUTICAL, INC.

101 East Main Street
Little Falls, New Jersey 07424
Telephone: (973) 890-1440
Fax: (973) 890-7980

May 25, 2005

Bertek Pharmaceuticals Inc.
2898 Manufacturer Road
Greensboro, NC 27406
Attention: David Sumar

Supply and Distribution Agreement

Dear David:

We refer to the Supply and Distribution Agreement dated as of August 5, 1999 (the "Agreement"), by and between Mylan Laboratories, Inc., Bertek Pharmaceuticals, Inc. and Amide Pharmaceutical, Inc. ("API").

As you may be aware, Amide Holdings, Inc. ("Amide") has entered into an agreement with Actavis Group hf, a corporation organized under the laws of Iceland ("Actavis") pursuant to which Actavis or one of its affiliates would acquire all of the outstanding shares of Amide and its wholly-owned subsidiary, API. Under the terms of the transaction, Actavis or its affiliate would acquire Amide directly and therefore indirectly become the new owner of API's generic pharmaceutical business. While we do not believe the transaction would constitute an "assignment" within the meaning of Section 13.1 of the Agreement, we would also like to clarify that you would not take a contrary view.

In order to permit API and Mylan/Bertek to continue its commercial relations under the Agreement without interruption, Amide has requested that Mylan/Bertek waive any and all termination or consent rights it may have under this Agreement (whether under Section 13.1 or otherwise) resulting from the consummation of any transaction between Actavis and Amide that is consistent with the description provided in the previous paragraph. The waiver set forth in this letter applies only to the transaction described in the second paragraph above and does not constitute a waiver of any other right or a waiver with respect to any other transaction.

Please confirm your agreement to the foregoing by executing and returning a copy of this letter to me at your earliest convenience.

I thank you for your prompt attention to our request and we look forward to continuing our productive relationship with you in the future.

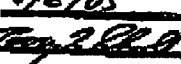
Very truly yours,

AMIDE PHARMACEUTICAL, INC.

BERTEK PHARMACEUTICALS, INC.

Acknowledged and agreed:

By: 
Divya C. Patel
President

APPROVED AS TO FORM
MYLAN LEGAL DEPT.
DATE: 6/8/05
BY: 

By: 
Name: David Sumar
Title: Chief Financial Officer

6-8-05

HIGH QUALITY PHARMACEUTICALS

Note to file BD-35.4:
No B.C.R.A. form needed
for this matter since there
is no new contractual
commitment only acknowledge-
ment by the parties that
the existing contract remains
in effect following acquisition
of Amide by Actavis
6/27/05 JLS